MEETING MINUTES
OF THE
CENTERS FOR MEDICARE AND MEDICAID SERVICES
MEETING OF THE
MEDICARE COVERAGE ADVISORY COMMITTEE

March 12, 2003

Baltimore Convention Center
One West Pratt Street
Baltimore, Maryland

Medicare Coverage Advisory Committee Meeting

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Attendees

Harold C. Sox, M.D.
Chairperson

Kimberly Long
Executive Secretary

Voting Members
Wade M. Aubry, M.D.
Norman Daniels, M.D.
Alan M. Garber, M.D.
Clifford Goodman, Ph.D.
Tracy R. Gordy, M.D.
Mark Slaughter, M.D.
Louise Woerner

CMS Liaison
Steve E. Phurrough, M.D., M.P.A.

Consumer Representative
Linda A. Bergthold, Ph.D.

Industry Representative
Eileen C. Helzner, M.D.

Non-Voting Guest Panelists
George J. Agich, M.D.
Stephen Gottlieb, M.D.
Joanne Lynn, M.D., M.A., M.S.
Ileana L. Pina, M.D.
Julie Swain, M.D.

Wednesday, March 12, 2003, 8:04 a.m.

The Medicare Coverage Advisory Committee met on March 12, 2003, to hear and discuss evidence and testimony regarding the use of a ventricular assist device as destination therapy in end-stage heart failure patients who are not eligible for a heart transplant.

The meeting began with the introduction of the Committee, a reading of the conflict of interest statement, and opening remarks by the CMS Liaison.

CMS Presentation of Request and Voting/Discussion Questions.

Perry Bridger described the impact of congestive heart failure on the Medicare population, presented the panel with the history and time line of Medicare coverage for VAD devices, gave an overview of the current coverage request, and presented the panel with the following voting question:

Is the quality of the evidence adequate to draw conclusions about the net health outcomes in Medicare beneficiaries meeting the REMATCH trial criteria who undergo LVAD implantation?

Mr. Bridger also informed the panel of the following statements concerning the REMATCH trial, and related discussion questions that CMS would like the panel's comments on:

One: **REMATCH showed increased survival in device recipients, but the survival advantage diminished over time and was associated with severe complications and increased hospitalization. Do the demonstrated extension of life and the limited improvement in the quality of life justify the risks of LVAD implantation?**

Two: **One REMATCH inclusion criterion is that candidates for LVAD implantation for destination therapy could not be a heart transplant candidate. Should the evaluation to determine transplant candidacy be performed only by a heart transplant center that has been approved for Medicare reimbursement?**

Three: **Initially, should treatment centers using LVAD meet specific facility and personnel requirements in order to provide the patient with an optimal chance of successful outcomes following LVAD implantation?**

Four: **REMATCH results are based on LVAD implantation in 68 patients. Complete, timely, and accurate LVAD implant and outcomes data for destination therapy patients is critical for future Medicare coverage review and policy refinements. Should data reporting be required as a condition for Medicare reimbursement?**

Five: **There have been improvements in both LVAD design and medicine management of end-stage heart failure patients since the start of the REMATCH trial. Have these improvements affected the applicability of the REMATCH results?**

Requestor's Presentation.

Dr. Eric Rose, Dr. James Long, and Dr. Leslie Miller addressed the panel. Their presentations included summaries of the trial process and results; videos showing some recipients of an LVAD implant; a history of the development of the LVAD device and changes that have been made to the device since the REMATCH trial commenced. They also discussed the issues of infection, adverse events, survival, nutrition, and patient management for LVAD recipients.

The requestors stated that REMATCH was a well designed trial with high quality evidence that can be used to answer the voting question and that the net health outcome of device patients is substantially more effective than medically managed patients. They also commented positively on the five discussion questions posed by CMS to the panel.

Scheduled Public Comments.

The panel heard from five speakers who had requested the opportunity to address the panel. These speakers included representatives of the International Society for Heart and Lung Transplantation, American College of Cardiology, the Society of Thoracic Surgeons and American Association for Thoracic Surgery, the American Society of Transplant Surgeons, and the American Heart Association.

Collectively, these speakers strongly endorsed the use of LVADs for certain patients ineligible for cardiac transplantation, but stressed the importance of ensuring that these patients met REMATCH criteria, and that providers be required to submit outcomes data to a centralized registry.

Open Panel Deliberations.

As the primary reviewer on the MCAC LVAD panel, Dr. Aubry gave his evaluation of the methodology in the REMATCH trial. As a second designated reviewer for the MCAC LVAD panel, Dr. Slaughter described several clinical issues for the panel's consideration. Following these presentations, the panel asked questions of the REMATCH investigators.

Open Public Comments.

Two members of the public had signed up at the meeting to address the panel. However, when called upon, they both stated that they would defer their comments and

contribute their time to the panel deliberations and discussions with the REMATCH investigators.

Open Panel Deliberations and Voting.

The panel conducted extensive discussions, including asking many additional questions of the REMATCH investigators. Following the discussion, it was moved and seconded that the panel change the voting question to read as follows:

> "Is the quality of the evidence adequate to draw conclusions about the net health outcomes in Medicare beneficiaries comparable to the patients enrolled in the REMATCH trial who undergo LVAD implantation?"

Prior to taking a vote, Dr. Sox asked each voting member, as well as the consumer and industry representatives, to summarize their conclusions based on the evidence and the panel deliberations. Following these statements, a vote was taken. The results of the vote were six to one in favor of the question.

The panel then discussed the appropriate effect size for the improvement of net health outcomes of LVADs compared to optimal medical management for these patients. A motion was made and seconded that the procedure is effective and falls into the "substantially more effective" category on magnitude of net health outcomes. Following discussion, the panel voted five to two on this motion. The two panelists who cast a negative vote commented that they considered the effect size to fall in the "more effective" category.

Discussion Questions.

Dr. Phurrough asked the panelists, including the consumer, industry representatives, and the non-voting guest panelists, to comment on each of the discussion questions. He noted

that the panel's recommendation on the voting question is just one of many criteria that CMS considers in arriving at a coverage decision, and that all comments about the discussion questions would be in the record of the meeting and would be considered by CMS. After the panelists had made their comments on discussion questions one through four, it was decided that discussion question five had been adequately addressed by earlier comments and further discussion was not needed.

Adjournment. The meeting adjourned at 3:35 p.m.

I certify that I attended the meeting of the Medicare Coverage Advisory Committee on February 12, 2003, and that these minutes accurately reflect what transpired.

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Kimberly Long
Executive Secretary, MCAC, CMS

I approve the minutes of this meeting as recorded in this summary.

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Harold C. Sox, M.D.
Chairperson